

Claims

1. A method to reduce the likelihood of the occurrence of false outcomes of a test for detecting the presence or absence of prion protein in a biological sample comprising providing the sample with a substrate and a proteolytic enzyme and contacting the enzyme with said substrate to allow conversion of the substrate by the enzyme into a detectable product allowing monitoring the activity of said enzyme in a test sample.
2. A method according to claim 1 wherein said false outcomes comprise a false-positive outcome.
3. A method according to claims 1 or 2 wherein the outcome of said test essentially relies on the activity of said enzyme.
4. A method according to claims 1 to 3 wherein the activity of said enzyme in said test sample may be affected by an internal and/or external factor.
5. A method according to claims 1 to 4 wherein said test comprises digestion of prion protein and wherein the size of prion protein following digestion is not monitored.
6. A method according to anyone of claims 1 to-5 wherein said test comprises determining the presence of a prion protein in a sample using an antibody reactive with a prion protein.
7. A method according to claim 6 wherein said antibody reacts with both the normal and the pathogenic prion protein.

8. A method according to anyone of the preceding claims wherein said proteolytic enzyme is proteinase K or a functionally equivalent protease.

5 9. A method according to anyone of the preceding claims wherein said substrate is suitable for digestion by proteinase K.

10. A method according to anyone of claims 1 to 9 wherein said substrate is a chymotrypsin substrate.

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11. A method according to anyone of claims 1 to 9 wherein said substrate is casein-resorufin.

12. A method according to anyone of claims 1 to 9 wherein said
15 substrate is N-succinyl-Ala-Ala-Pro-Phe-p-NitroAnilide (SAAPPN).

13. A method according to anyone of claims 1 to 9 wherein said substrate has an enzymatic label.

20 14. A method according to anyone of claims 1 to 9 wherein said substrate is a fluorescent protein.

15. A method according to anyone of claims 1 to 9 wherein said substrate is a radiolabelled protein.

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16. Use of a method according to anyone of the preceding claims to monitor protease activity in each individual test sample in a test which essentially depends on proteolytic digestion so that the reliability of the outcome of such a test can be determined for each test sample.

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